

## **COMPREHENSIVE® REVERSE SHOULDER Mini BasePlate PROTOCOL**

PROTOCOL NUMBER (Study ID): INT.CR.GE1  
PROTOCOL VERSION: V. **July, 31, 2014**

### **Purpose and Objectives**

The primary objective of this prospective clinical data collection is to evaluate survivorship for the Biomet® Comprehensive® Reverse Shoulder Mini Baseplate. Secondary objectives include validation of implant sizing and hardware options as well as collection of mid-term clinical outcomes including adverse events, scapular notching, and Constant Score.

All shoulders on which data will be collected are legally marketed and none of the devices are investigational or experimental. FDA has cleared this device via Premarket Notification 510(k) K080642. This data collection effort will document the clinical outcomes of the Comprehensive® Reverse shoulders. The data gathered will be collated and used to provide feedback to designing engineers, support marketing efforts, and answer potential questions from reimbursement agencies.

Inclusion/exclusion criteria are the same as the indications and contraindications stated in the labeling. Surgical techniques and patient care are to be standard for the surgeon participating in the protocol. There will be no experimental or investigational surgical techniques used. The devices and products are to be used in accordance with their instructions for use and/or approved labeling.

The outcomes and data collected include:

- Survivorship (including glenoid loosening)
- Adverse Events (including dislocation)
- Constant-Murley Shoulder Score
- Radiographic Evaluation (Plain X-ray and CT)
- Scapular Notching
- American Shoulder and Elbow Surgeons (ASES) Assessment
- Visual Analogue Scale (VAS) for patient satisfaction

Survivorship will be documented by asking the surgeon to record revisions, complications, and device related events.

### **Project Overview**

One-hundred (100) cases will be enrolled in this data collection effort and 3-year follow-up will be attempted. Follow-up will be scheduled for 0 - 6 weeks, 6 months, 1 year and 3 years post operatively. Follow-up assessments include the Modified Constant shoulder

assessment, American Shoulder and Elbow Surgeon Assessment (ASES), VAS for patient satisfaction, and Radiographic Evaluation (plain radiographs and CTs).

## Patient Population

A sample size of 100 Comprehensive® Reverse Shoulder cases which utilize the Mini Baseplate and mini stem will be sought for the study. Bilateral shoulders may be included in the study as separate cases. Any case requiring removal of any component will be considered a failure and the revised shoulder may be enrolled into the study as a new case.

An effort will be made to obtain consecutive cases from each site. However, because the patients have the right to refuse to participate in the study but still receive a Comprehensive® Reverse Shoulder, consecutive cases may not be achieved.

## Sample Size Calculation / Justification

Because this is a one-arm observational study with no control group the sample size for this study is based on the goal of having a reasonable number of cases for evaluating device survival over the first 3 years of follow-up. An article by Frederick Dorey, et. al. in the Journal of Arthroplasty recommends having greater than 20 subjects in follow-up when estimating survivorship<sup>1</sup>. Other device registries use a population of 40 as a “rule of thumb” for survivorship analysis. Loss to follow-up for this study is estimated to be 10% per year. Thus, if 100 patients are enrolled, there will be 73 patients at 3 years of follow-up.

Start with 100 cases and assume a loss of 10% per year

$$\begin{aligned}1\text{-year: } & 100 - 10 = 90 \\2\text{-year: } & 90 - 9 = 81 \\3\text{-year: } & 81 - 8 = 73\end{aligned}$$

Therefore, a starting population of 100 cases will be more than adequate to provide a reasonable evaluation of survivorship at 3 years per Dorey, et. al.

This sample size is adequate to provide a precise estimate of the mean Constant score at the 3-year time point. The “precision” is based on a 95% confidence interval, calculated based on the normal distribution, for the mean Constant score at 3 years, and refers to the distance from the estimated parameter (point estimate) to the upper and lower limits of the confidence interval. The full width of the confidence interval is twice the precision. In an article by Ballas, et al.<sup>2</sup>, the standard deviation of the postoperative constant scores for 56 reverse shoulders at a mean follow-up of 58 months was 12 points. Assuming a standard deviation of 12 points

<sup>1</sup> Dorey, Frederick and Harlan C. Amstutz. “Survivorship Analysis in the Evaluation of Joint Replacement.” *Journal of Arthroplasty*. Vol. 1 No. 1, March 1986. pp 63-69.

<sup>2</sup> Ballas, Richard et al. “Results of a stemless reverse shoulder prosthesis at more than 58 months mean without loosening.” *J Shoulder Elbow Surg* (2013)

and 73 patients available at the 3 year follow-up, the precision of a 95% confidence interval for the mean would be +/- 2.8 points.

## Inclusion Criteria

The inclusion criteria are the same as the indications stated in the cleared labeling for the device, specifically:

*Biomet® Comprehensive® Reverse Shoulder products are indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.*

*The Comprehensive® Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.*

*Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. The Glenoid Baseplate components are intended for cementless application with the addition of screw fixation.*

*Interlok™ finish humeral stems are intended for cemented use and the MacroBond™ coated humeral stems are intended for press-fit or cemented applications. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.*

Therefore, patients / cases to be included in this study shall utilize the following inclusion criteria:

1. Comprehensive Reverse Shoulder Mini Base Plate and Mini Stem in a reverse shoulder configuration.
2. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.
3. Grossly deficient rotator cuff with severe arthropathy and/or
  - a. Previously failed shoulder joint replacement with a grossly deficient rotator cuff.
  - b. Primary total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency, or
  - c. Fracture total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency, or
  - d. Revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

## **Exclusion Criteria**

The exclusion criteria are the same as the indications stated in the cleared labeling for the device:

Absolute contraindications include infection, sepsis, and osteomyelitis.

Relative contraindications include:

1. Uncooperative patient or patient with neurologic disorders who is incapable or unwilling to follow directions.
2. Osteoporosis.
3. Metabolic disorders which may impair bone formation.
4. Osteomalacia.
5. Distant foci of infections which may spread to the implant site.
6. Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram.

## **HIPAA Compliance**

Compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) is required and data collection must comply with the Standards for Privacy of Individually Identifiable Health Information, 45 CFR Part 160 and Part 164, as amended from time to time (the “Privacy Rule”), under HIPAA.

The case report forms do not include any patient identifying information in accordance with HIPAA. Therefore, once the data is entered in the online database a patient can no longer be identified. It is the responsibility of the investigator to maintain a list of patient identification and Joint Assist ID numbers.

By assigning patients a unique Joint Assist ID number, their identity is protected in Joint Assist, the online database. The database is restricted, allowing a doctor to only view and enter data from his own patients. User authentication is required to view research data. The data is transmitted to a centralized database through a secured (SSL) channel on the Internet. Data in transit is in 128-bit encryption. The access to the centralized database is limited to those who are responsible for maintaining the database.

## **Case Report Form Completion**

All sites will be required to complete and submit patient case report forms on Biomet’s online database Joint Assist (<https://www.jointassist.com>) in a timely manner. Forms will be monitored for completeness and accuracy. It is imperative that the investigator answers all questions on the case report forms.

## **Data Retention and Destruction**

All information entered into the Joint Assist Database will be stored indefinitely. Each participating investigator will only have the opportunity to view their patient information. Other individuals having access to the de-identified patient data outside of the surgeons' site are the Biomet Study Manager and Biomet's Clinical Data Coordinator who oversees the Joint Assist database. It is up to the investigators discretion on whether they give their research assistant(s) access to the Joint Assist program.

The investigator will be responsible for retaining, hardcopy, source documents for their files.

## **Treatment**

The surgeons will follow preoperative and postoperative routine standards of care for patients undergoing total shoulder replacement surgery. All patients will receive a Biomet® Comprehensive® Reverse Shoulder Mini Baseplate and mini stem.

## **Monitoring**

The site will be required to complete study forms by electronic submission, in a timely manner to the Biomet database. Forms will be monitored for completeness and accuracy. It is imperative that investigators answer all questions on the case report forms.

Monitoring of protocol deviations, to ensure that the study is being conducted consistent with the protocol, and subject rights violations is planned at least annually. This monitoring will be performed by the Clinical Research Coordinator in Korea (Anna Lee).

## **Data Collection**

This is an observational study, and once patients are enrolled and surgeries completed, they will be followed-up at:

- 0 – 6 weeks,
- 6-months,
- 1-year and
- 3-years.

### **A. Demographic Data**

The demographic data will be collected at the preoperative visit. Please see the Historical Record in the Case Report Forms for the variables collected.

### **B. Operative Data**

The operative data will be collected during or immediately following surgery. Please see the attached Operative Record in the Case Report Forms for the variables collected.

### C. Clinical Data

#### 1. Data Collection Periods and Assessment

- a. Preoperative Exam
- b. Operative Report
- c. 0 to 6 weeks post-op
- d. Six Month Follow-Up Exam (-3 months, +3 months)
- e. One Year Follow-Up Exam (-3 Months, +12 Months)
- f. Three Year Follow-Up Exam ( $\pm$ 12 Months)

#### 2. Assessment

- a. Modified Constant Assessment
- b. Radiographic Evaluation (including scapular notching)
- c. ASES
- d. VAS
- e. Complications/Lost to Follow-Up

Form	Enrollment	Pre-op Exam	Surgery	0 – 6 Wk post-op	6-Months post-op	1-year post-op	3-year post-op
Enrollment & Consent	X						
Pre-op Hx/Demographics		X					
Surgical Form			X				
Constant Score		X		X	X	X	X
ASES		X		X	X	X	X
VAS		X		X	X	X	X
Radiographic Assessment		X		X	X	X	X
CT				X		X	X
CT Assessment				X		X	X
Adverse Events			As Needed	As Needed	As Needed	As Needed	As Needed
Lost To Follow-up			As Needed	As Needed	As Needed	As Needed	As Needed
Protocol Deviation	As Needed	As Needed	As Needed	As Needed	As Needed	As Needed	As Needed

### D. Radiographic Data

A true external rotation AP view of the shoulder and an axillary view of the shoulder will be taken at the pre-operative, 0 to 6 weeks, 6 months, 1-year and 3-year follow-up visits. Radiographs must be de-identified and uploaded as a picture file to the Joint Assist database. Radiographic data will be used to evaluate the presence of scapular notching at each follow-up visit.

CT data will also be collected at the first post-operative follow-up, the 1-year follow-up and the 3-year follow-up. The protocol for performing the CT can be found in Appendix A.

#### **E. Complications**

It is the responsibility of the investigator to identify and report all complications in the Joint Assist Database. The following definition will be used in this data collection:

**Complication:** Any untoward medical occurrence in a patient administered a medical device and which does not necessarily have to have a causal relationship with this treatment. A complication can, therefore, be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a device, whether or not considered related to this device.

#### **F. Complaints**

Complaints and events reportable under FDA's MedWatch Regulations should also be reported to Biomet's Regulatory Department (800-348-9500 ext. 1305).

### **Definitions**

**Inferior Notching:** An erosion of the scapular neck in proximity to the glenoid prosthesis. Classified by the Nerot grading system.

**Anterior Notching:** Any glenoid radiolucency disrupting the normal contour of the lateral bone adjacent to the glenosphere anteriorly.

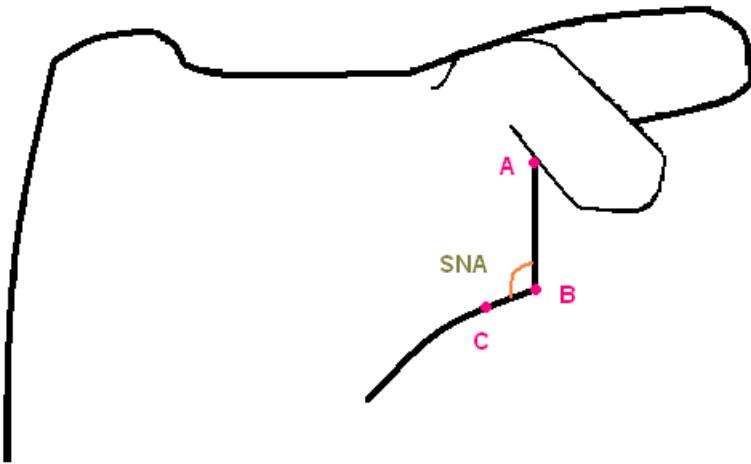
**Posterior Notching:** Any glenoid radiolucency disrupting the normal contour of the lateral bone adjacent to the glenosphere posteriorly.

**Scapular Neck Angle (SNA):** The angle subtended by the intersection of line AB and line BC. Point C is located 1 cm medial to the most inferior and lateral bone of the inferior glenoid rim.

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## **Annual Reports**

The study sponsor will present an annual report to the study investigators that will include a summary of the clinical data.

## **Analysis / Reports**

Data collected as part of this study will be used to evaluate:

- Survivorship (including glenoid loosening)
- Adverse events (including dislocation)
- Constant Scores
- Radiographic results for both plain radiographs and CT images (including scapular notching)
- Analysis may also include 3D reconstructions of CT scans and further analysis of implant sizing

## **Patient Withdrawal**

It is recognized that the subject's participation in this trial is entirely voluntary, and that she/he may refuse to participate and may withdraw from participation at any time without jeopardy to any future medical care. It is also recognized that the investigator, at his/her discretion, may withdraw a subject from this study based upon his/her professional judgment. In event of subject withdrawal, applicable local procedures should be followed

## **Risk Analysis**

The following possible adverse effects are associated with shoulder replacement surgery as stated in the package insert for this device.

## WARNINGS

Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. The use of a reverse shoulder prosthesis in patients with a deficient rotator cuff could increase the risk of component loosening due to non-anatomic loading conditions. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris or fatty tissue have lower adhesion strength to cement than implants handled with clean gloves. Improper preoperative or intra-operative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.

1. Humeral and glenosphere components should be used only when there is good quality bone.
2. Disassociations of modular components have been reported. Failure to properly align and completely seat the components together can lead to disassociation. Thoroughly clean and dry tapers prior to attachment of modular components to avoid crevice corrosion and improper seating. All additional locking screws must be adequately tightened.
3. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations that may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported.

Biomet® joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals, they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitations of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma and excessive weight bearing have been implicated with premature failure of the implant by loosening, fracture, and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone, making successful revision surgery more difficult. The patient is to be made aware

and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician, including follow-up visits.

## **PRECAUTIONS**

Patient selection factors to be considered include: 1) need to obtain pain relief and improve function, 2) ability and willingness of the patient to follow instructions, including control of weight and activity levels, 3) a good nutritional state of the patient and 4) the patient must have reached full skeletal maturity, and the patient must have a functional deltoid muscle.

Specialized instruments are designed for Biomet® joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, incorrect sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments that have experienced extensive use or excessive force are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, placed in a different patient.

## **POSSIBLE ADVERSE EFFECTS**

1. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis, or osteolysis may be a result of loosening of the implant.
2. Early or late postoperative infection and allergic reaction.
3. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
4. Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption and/or excessive activity.
5. If glenoid component is not securely fixed, micromotion can lead to peripheral screw failure.
6. Periarticular calcification or ossification, with or without impediment of joint mobility.

7. Inadequate range of motion due to improper selection or positioning of components, lack of rotator cuff, and inadequate function of the deltoid.
8. Undesirable shortening or lengthening of limb.
9. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity or excessive activity can also contribute to these conditions.
10. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
11. Fretting and crevice corrosion can occur at interfaces between components.
12. Wear and/or deformation of articulating surfaces.
13. Intraoperative or postoperative bone fracture and/or postoperative pain.
14. Scapular notching and bone erosion has been reported with the use of reverse shoulder implants. Scapular notching may lead to early failure of glenoid fixation.

## Reports

The sponsor will present an annual report to the investigators that will include a summary of the clinical data. The report will contain the results of:

- Survivorship
- Adverse Events
- Modified Constant Score
- Incidence of scapular notching
- List of reported complications.

Patient follow-up will be analyzed throughout the data collection according to the following definition and equations:

### Lost To Follow-Up:

1. Death
2. Revision
3. Consent Rescinded

$$\text{Percentage Follow-up} = \frac{\text{# Patients with Follow-Up}}{\text{(Theoretically due - Lost To Follow-Up)}} \times 100$$

$$\text{Percentage Accounted for} = \frac{(\text{# with Follow-Up} + \text{Lost To Follow-Up})}{\text{Theoretically due}} \times 100$$

At the end of the data collection, a final report will be compiled that will summarize all data collected, complications reported, and general findings.

## Appendix A

### CT Protocol

#### **General Scan Requirements**

Computerized Tomography (CT) is required for Signature Guide production. Scanners must have ability to scan 0.5mm or 0.625mm thickness.

#### **Patient Position**

Patient is positioned on the scanning couch in the supine position with hand of side of interest PALM “up” in anatomical position. Sandbag or other immobilizing device should be used to maintain patient position.

#### **Scan Parameters**

**AXIAL** images are acquired from above the acromion process to below the inferior angle of the scapula. Slices are positioned perpendicular to the glenoid fossa or parallel to the scapular spine. The **entire** scapula and adjacent humerus must be included in the FOV. Use the smallest FOV possible to acquire all boney anatomy of the scapula and adjacent humerus.

Axial Helical or contiguous slices .625mm or less

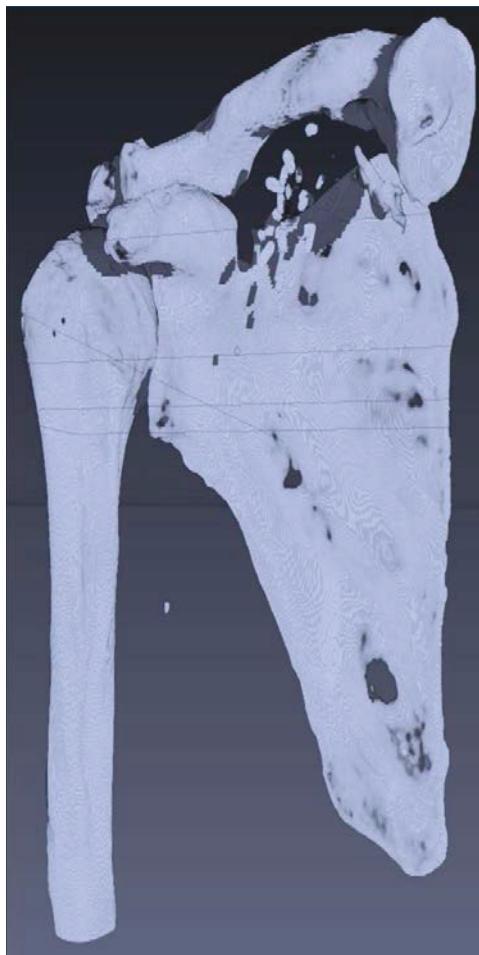
FOV 250mm or smallest to include all boney anatomy of scapula AND adjacent humerus anatomy (see figure 2)

Soft tissue algorithm

512 x 512 matrix

120 kVp

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**Anterior View**

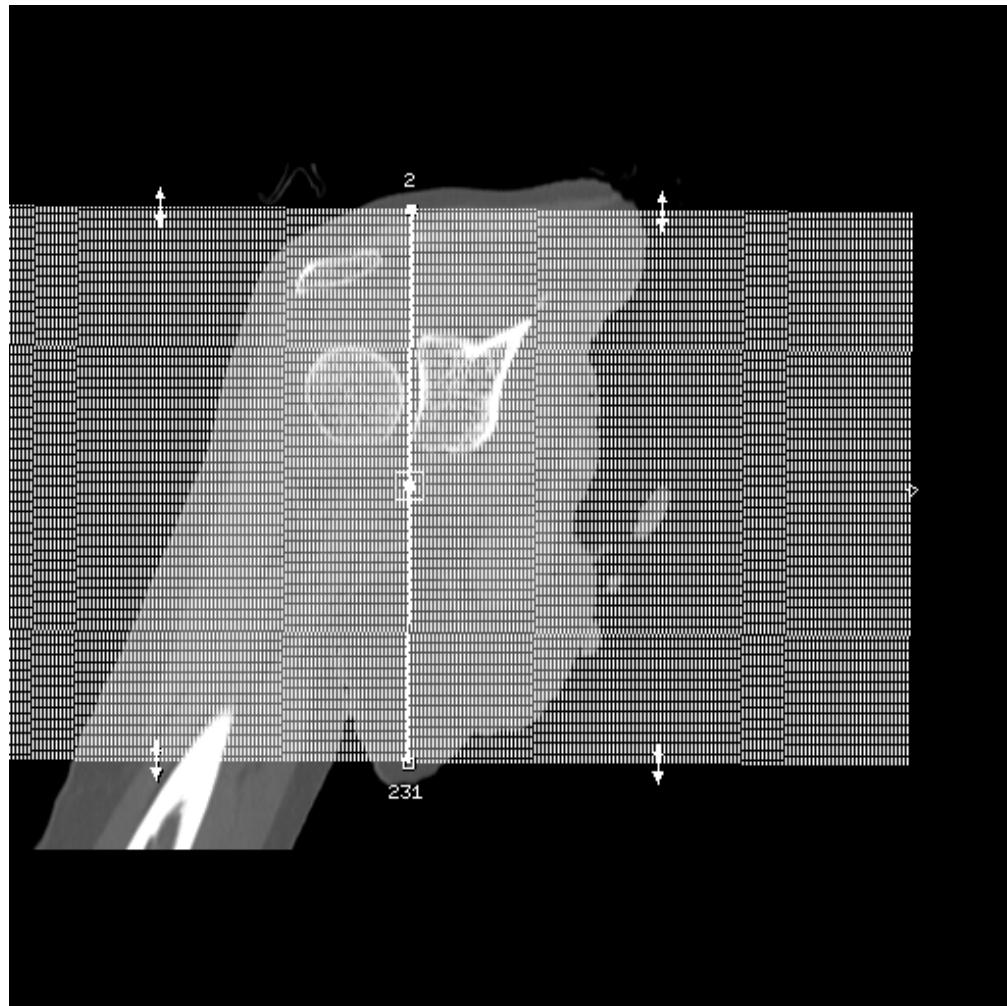
**Posterior View**

Figure 1 – All bony anatomy of the scapula to be included with adjacent humeral head and shaft

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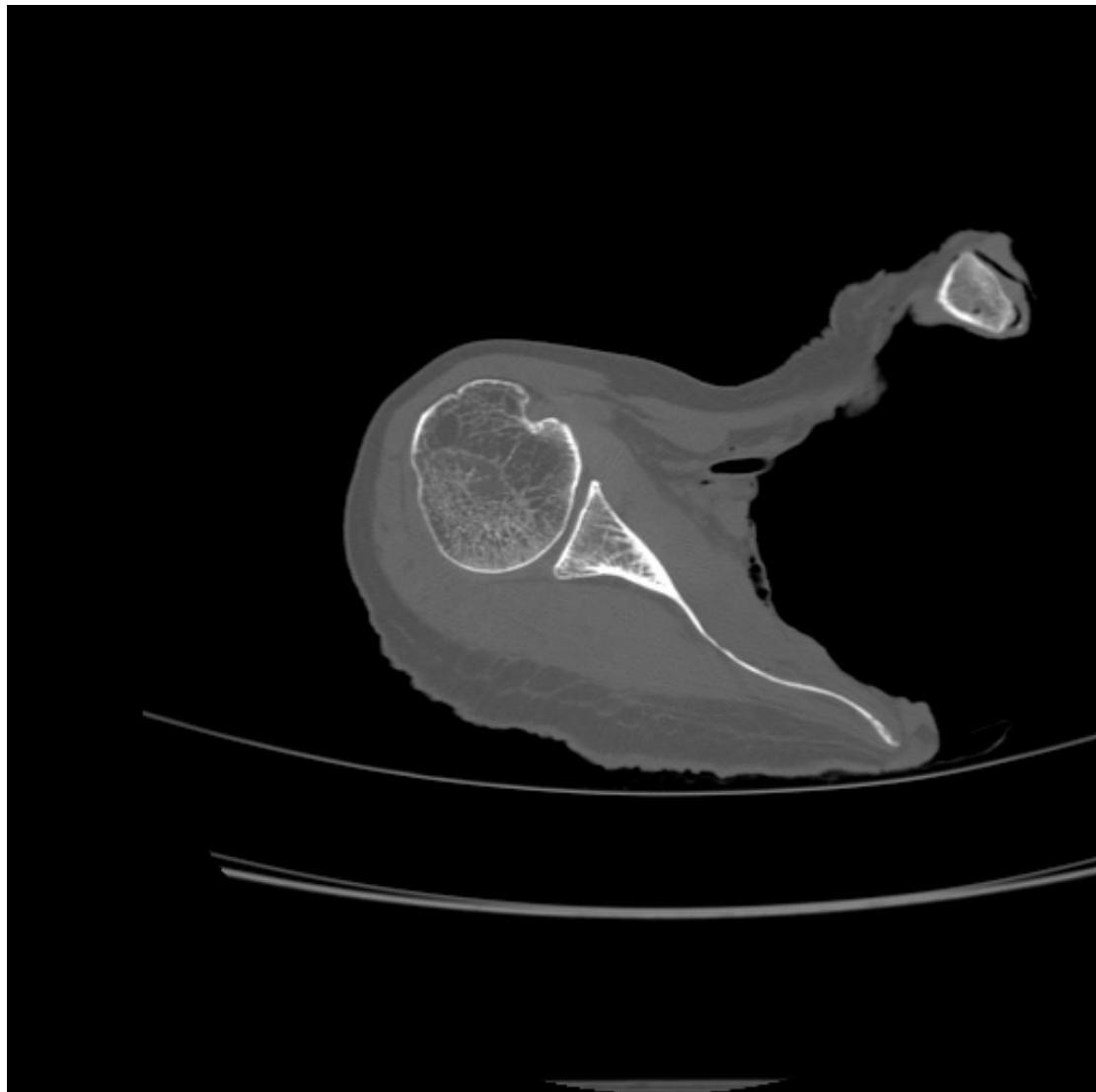


**Figure 2** FOV to include all of boney anatomy of scapula and adjacent humerus below the level of the inferior scapular angle

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**Figure 3 Axial CT Images from above acromion process to below inferior angle of scapula**

Only axial images are required. No image reformats are needed. Images should be transmitted in uncompressed DICOM format via the Biomet Virtual PACS (MedWeb) in the original acquired thickness.

Frequently asked questions:

**Does the position of the hand make a difference?** Yes. The hand should be positioned palm up to allow the best visualization of anatomy of interest.

**Can I scan with a thicker slice and reformat to 0.5mm or 0.625mm?** No. Images must be acquired at a thickness of 0.625mm or less.

**Will reformats in the coronal and Sagittal planes help?** No. And the transmission of these additional images may hinder the transmission of the required image set.

**How will I know if my images are good?** If there is a need to rescan a patient you will be contacted by a Biomet Signature representative.

**How do I evaluate my images to know they are adequate?** Confirm the below:

1. There is no motion evident
2. All bony scapula anatomy and adjacent humeral anatomy are present
3. The images are acquired with the soft tissue algorithm
4. The slice thickness is not greater than 0.625mm
5. The FOV is not greater than 250mm

**Who can I call if I have other questions?** [Clinical Research Coordinator in Korea: Anna Lee \(82 70 7123 6337\)](#)

## Clinical Protocol Change History

From Version	To Version	Description of Change	Page number	Study Manager approval	Director Approval
		Initial version			